



EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of health claims related to foods with reduced amounts of sodium and maintenance of normal blood pressure (ID 336, 705, 1148, 1178, 1185, 1420) pursuant to Article 13(1) of Regulation (EC) No 1924/2006

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SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to foods with reduced amounts of sodium and maintenance of normal blood pressure (ID 336, 705, 1148, 1178, 1185, 1420) pursuant to Article 13(1) of Regulation (EC) No 1924/2006¹

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)^{2, 3}

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

Following a request from the European Commission, the Panel on Dietetic Products, Nutrition and Allergies was asked to provide a scientific opinion on a list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006. This opinion addresses the scientific substantiation of health claims in relation to foods with reduced amounts of sodium and maintenance of normal blood pressure. The scientific substantiation is based on the information provided by the Member States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

The food constituents that are the subjects of the health claims are “sodium/salt”, “low sodium/salt and/or increased potassium”, “food reduced/low in/free of sodium/salt and/or increased potassium”, “breads with salt content of <0.7 %”, and “natural berries/sodium”. From the information provided, the Panel assumes that the food constituent that is the subject of the health claims is sodium, which should be reduced in foods in order to obtain the claimed effect. The Panel considers that the food constituent, sodium, which is the subject of the health claim, is sufficiently characterised.

The claimed effects are “effects on blood pressure”, “heart health”, “blood pressure, heart health”, and “cardiovascular system”. The Panel assumes that the target population is the general population. In the context of the proposed wordings, the Panel notes that the claimed effect relates to the maintenance of normal blood pressure. The Panel considers that maintenance of normal blood pressure is a beneficial physiological effect.

¹ On request from the European Commission, Question No EFSA-Q-2008-1123, EFSA-Q-2008-1492, EFSA-Q-2008-1887, EFSA-Q-2008-1917, EFSA-Q-2008-1924, EFSA-Q-2008-2157, adopted on 25 March 2011.

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³ Acknowledgement: The Panel wishes to thank for the preparatory work on this scientific opinion: The members of the Working Group on Claims: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Marina Heinonen, Hannu Korhonen, Martinus Løvik, Ambroise Martin, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Inge Tetens, Hendrik van Loveren and Hans Verhagen. The members of the Claims Sub-Working Group on Cardiovascular Health/Oxidative Stress: Antti Aro, Marianne Geleijnse, Marina Heinonen, Ambroise Martin, Wilhelm Stahl and Henk van den Berg.

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The evidence provided by consensus opinions/reports from authoritative bodies and reviews shows that there is good consensus on the effect of sodium intake on blood pressure in normotensive and hypertensive human subjects.

The Panel concludes that a cause and effect relationship has been established between high dietary sodium intakes and increased blood pressure, and that the reduction of dietary sodium intake helps maintain a normal blood pressure.

To establish conditions of use, sodium/salt nutrition claims as per Annex of Regulation (EC) No 1924/2006 should be considered. The target population is the general population.

KEY WORDS

Sodium, blood pressure, health claims.

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BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION

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TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

See Appendix A

EFSA DISCLAIMER

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INFORMATION AS PROVIDED IN THE CONSOLIDATED LIST

The consolidated list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006⁴ submitted by Member States contains main entry claims with corresponding conditions of use and literature for similar health claims. EFSA has screened all health claims contained in the original consolidated list of Article 13 health claims which was received by EFSA in 2008 using six criteria established by the NDA Panel to identify claims for which EFSA considered sufficient information had been provided for evaluation and those for which more information or clarification was needed before evaluation could be carried out⁵. The clarifications which were received by EFSA through the screening process have been included in the consolidated list. This additional information will serve as clarification to the originally provided information. The information provided in the consolidated list for the health claims which are the subject of this opinion is tabulated in Appendix C.

ASSESSMENT

1. Characterisation of the food/constituent (ID 336, 705, 1148, 1178, 1185, 1420)

The food constituents that are the subjects of the health claim are “sodium/salt”, “low sodium/salt and/or increased potassium”, “food reduced/low in/free of sodium/salt and/or increased potassium”, “breads with salt content of <0.7 %”, and “natural berries/sodium”.

A claim on potassium and maintenance of normal blood pressure has been already evaluated with a favourable outcome (EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2010).

From the information provided, the Panel assumes that the food constituent that is the subject of the health claim is sodium, which should be reduced in foods in order to obtain the claimed effect.

Sodium is a well recognised nutrient and is measurable in foods by established methods.

Sodium is naturally present in foods as a normal constituent at a low level. It is also added to foods, mainly as sodium chloride (commonly known as salt) during processing, cooking and immediately prior to consumption, but also as sodium nitrate, sodium phosphate or sodium glutamate. Sodium is authorised for addition to foods (Annex I of the Regulation (EC) No 1925/2006⁶ and Annex I of Directive 2002/46/EC⁷). This evaluation applies to sodium naturally present in foods and added to foods.

The Panel considers that the food constituent, sodium, which is the subject of the health claims, is sufficiently characterised.

2. Relevance of the claimed effect to human health (ID 336, 705, 1148, 1178, 1185, 1420)

The claimed effects are “effects on blood pressure”, “heart health”, “blood pressure, heart health”, and “cardiovascular system”. The Panel assumes that the target population is the general population.

⁴ Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods. OJ L 404, 30.12.2006, p. 9–25.

⁵ EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), 2011. General guidance for stakeholders on the evaluation of Article 13.1, 13.5 and 14 health claims. EFSA Journal, 9(4):2135, 24 pp.

⁶ Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods. OJ L 404, 30.12.2006, p. 26–38

⁷ Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements. OJ L 183, 12.7.2002, p. 51–57.

In the context of the proposed wordings, the Panel notes that the claimed effect relates to the maintenance of normal blood pressure.

Blood pressure is the pressure (force per unit area) exerted by circulating blood on the walls of blood vessels. Elevated blood pressure, by convention ≥ 140 mmHg (systolic) and/or ≥ 90 mmHg (diastolic), may compromise the normal function of the arteries.

The Panel considers that maintenance of normal blood pressure is a beneficial physiological effect.

3. Scientific substantiation of the claimed effect (ID 336, 705, 1148, 1178, 1185, 1420)

The evidence provided by consensus opinions/reports from authoritative bodies and reviews shows that there is good consensus on the effect of sodium intake on blood pressure in normotensive and hypertensive human subjects. This evidence comes from large-scale prospective cohort studies, and from a number of well controlled intervention studies and meta-analysis of randomised controlled trials (Geleijnse et al., 2003; He and MacGregor, 2003; He et al., 2009; IoM, 2005; SCF, 1993; WHO, 2006). Whereas sodium intake generally shows an association (and potassium intake an inverse association) with blood pressure values and/or the risk of hypertension, the sodium/potassium ratio appears to be a stronger predictor of blood pressure than the intake of either electrolyte alone (IoM, 2005).

European and American professional associations recommend decreasing dietary sodium intakes for the prevention and management of human hypertension (Appel et al., 2006; Lichtenstein et al., 2006; Mancia et al., 2007), and biologically plausible mechanisms for this effect have been proposed.

The Panel concludes that a cause and effect relationship has been established between high dietary sodium intakes and increased blood pressure, and that the reduction of dietary sodium intake helps to maintain a normal blood pressure.

4. Panel's comments on the proposed wording (ID 336, 705, 1148, 1178, 1185, 1420)

The Panel considers that the following wording reflects the scientific evidence: "High sodium intakes increase blood pressure; consumption of foods low or very low in sodium helps to maintain normal blood pressure."

5. Conditions and possible restrictions of use (ID 336, 705, 1148, 1178, 1185, 1420)

To establish conditions of use, sodium/salt nutrition claims as per Annex of Regulation (EC) No 1924/2006 should be considered. The target population is the general population.

CONCLUSIONS

On the basis of the data presented, the Panel concludes that:

- The food constituent, sodium, which is the subject of the health claims, is sufficiently characterised.
- The claimed effects are "effects on blood pressure", "heart health", "blood pressure, heart health", and "cardiovascular system". The target population is assumed to be the general population. Maintenance of normal blood pressure is a beneficial physiological effect.

- A cause and effect relationship has been established between high dietary sodium intakes and increased blood pressure, and that the reduction of dietary sodium intakes helps to maintain a normal blood pressure.
- The following wording reflects the scientific evidence: “High sodium intakes increase blood pressure; consumption of foods low or very low in sodium helps to maintain normal blood pressure.”
- To establish conditions of use, sodium/salt nutrition claims as per Annex of Regulation (EC) No 1924/2006 should be considered. The target population is the general population.

DOCUMENTATION PROVIDED TO EFSA

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 (No: EFSA-Q-2008-1123, EFSA-Q-2008-1492, EFSA-Q-2008-1887, EFSA-Q-2008-1917, EFSA-Q-2008-1924, EFSA-Q-2008-2157). The scientific substantiation is based on the information provided by the Member States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

The full list of supporting references as provided to EFSA is available on: <http://www.efsa.europa.eu/panels/nda/claims/article13.htm>.

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SCF (Scientific Committee on Food), 1993. Report on nutrient and energy intakes for the European Community.

WHO (World Health Organization), 2006. Reducing salt intake in populations. Report of a WHO forum and technical meeting, 5-7 October 2006, Paris, France.

APPENDICES

APPENDIX A

BACKGROUND AND TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

The Regulation 1924/2006 on nutrition and health claims made on foods⁸ (hereinafter "the Regulation") entered into force on 19th January 2007.

Article 13 of the Regulation foresees that the Commission shall adopt a Community list of permitted health claims other than those referring to the reduction of disease risk and to children's development and health. This Community list shall be adopted through the Regulatory Committee procedure and following consultation of the European Food Safety Authority (EFSA).

Health claims are defined as "any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health".

In accordance with Article 13 (1) health claims other than those referring to the reduction of disease risk and to children's development and health are health claims describing or referring to:

- a) the role of a nutrient or other substance in growth, development and the functions of the body; or
- b) psychological and behavioural functions; or
- c) without prejudice to Directive 96/8/EC, slimming or weight-control or a reduction in the sense of hunger or an increase in the sense of satiety or to the reduction of the available energy from the diet.

To be included in the Community list of permitted health claims, the claims shall be:

- (i) based on generally accepted scientific evidence; and
- (ii) well understood by the average consumer.

Member States provided the Commission with lists of claims as referred to in Article 13 (1) by 31 January 2008 accompanied by the conditions applying to them and by references to the relevant scientific justification. These lists have been consolidated into the list which forms the basis for the EFSA consultation in accordance with Article 13 (3).

ISSUES THAT NEED TO BE CONSIDERED

IMPORTANCE AND PERTINENCE OF THE FOOD⁹

Foods are commonly involved in many different functions¹⁰ of the body, and for one single food many health claims may therefore be scientifically true. Therefore, the relative importance of food e.g. nutrients in relation to other nutrients for the expressed beneficial effect should be considered: for functions affected by a large number of dietary factors it should be considered whether a reference to a single food is scientifically pertinent.

⁸ OJ L12, 18/01/2007

⁹ The term 'food' when used in this Terms of Reference refers to a food constituent, the food or the food category.

¹⁰ The term 'function' when used in this Terms of Reference refers to health claims in Article 13(1)(a), (b) and (c).

It should also be considered if the information on the characteristics of the food contains aspects pertinent to the beneficial effect.

SUBSTANTIATION OF CLAIMS BY GENERALLY ACCEPTABLE SCIENTIFIC EVIDENCE

Scientific substantiation is the main aspect to be taken into account to authorise health claims. Claims should be scientifically substantiated by taking into account the totality of the available scientific data, and by weighing the evidence, and shall demonstrate the extent to which:

- (a) the claimed effect of the food is beneficial for human health,
- (b) a cause and effect relationship is established between consumption of the food and the claimed effect in humans (such as: the strength, consistency, specificity, dose-response, and biological plausibility of the relationship),
- (c) the quantity of the food and pattern of consumption required to obtain the claimed effect could reasonably be achieved as part of a balanced diet,
- (d) the specific study group(s) in which the evidence was obtained is representative of the target population for which the claim is intended.

EFSA has mentioned in its scientific and technical guidance for the preparation and presentation of the application for authorisation of health claims consistent criteria for the potential sources of scientific data. Such sources may not be available for all health claims. Nevertheless it will be relevant and important that EFSA comments on the availability and quality of such data in order to allow the regulator to judge and make a risk management decision about the acceptability of health claims included in the submitted list.

The scientific evidence about the role of a food on a nutritional or physiological function is not enough to justify the claim. The beneficial effect of the dietary intake has also to be demonstrated. Moreover, the beneficial effect should be significant i.e. satisfactorily demonstrate to beneficially affect identified functions in the body in a way which is relevant to health. Although an appreciation of the beneficial effect in relation to the nutritional status of the European population may be of interest, the presence or absence of the actual need for a nutrient or other substance with nutritional or physiological effect for that population should not, however, condition such considerations.

Different types of effects can be claimed. Claims referring to the maintenance of a function may be distinct from claims referring to the improvement of a function. EFSA may wish to comment whether such different claims comply with the criteria laid down in the Regulation.

WORDING OF HEALTH CLAIMS

Scientific substantiation of health claims is the main aspect on which EFSA's opinion is requested. However, the wording of health claims should also be commented by EFSA in its opinion.

There is potentially a plethora of expressions that may be used to convey the relationship between the food and the function. This may be due to commercial practices, consumer perception and linguistic or cultural differences across the EU. Nevertheless, the wording used to make health claims should be truthful, clear, reliable and useful to the consumer in choosing a healthy diet.

In addition to fulfilling the general principles and conditions of the Regulation laid down in Article 3 and 5, Article 13(1)(a) stipulates that health claims shall describe or refer to "the role of a nutrient or other substance in growth, development and the functions of the body". Therefore, the requirement to

describe or refer to the 'role' of a nutrient or substance in growth, development and the functions of the body should be carefully considered.

The specificity of the wording is very important. Health claims such as "Substance X supports the function of the joints" may not sufficiently do so, whereas a claim such as "Substance X helps maintain the flexibility of the joints" would. In the first example of a claim it is unclear which of the various functions of the joints is described or referred to contrary to the latter example which specifies this by using the word "flexibility".

The clarity of the wording is very important. The guiding principle should be that the description or reference to the role of the nutrient or other substance shall be clear and unambiguous and therefore be specified to the extent possible i.e. descriptive words/ terms which can have multiple meanings should be avoided. To this end, wordings like "strengthens your natural defences" or "contain antioxidants" should be considered as well as "may" or "might" as opposed to words like "contributes", "aids" or "helps".

In addition, for functions affected by a large number of dietary factors it should be considered whether wordings such as "indispensable", "necessary", "essential" and "important" reflects the strength of the scientific evidence.

Similar alternative wordings as mentioned above are used for claims relating to different relationships between the various foods and health. It is not the intention of the regulator to adopt a detailed and rigid list of claims where all possible wordings for the different claims are approved. Therefore, it is not required that EFSA comments on each individual wording for each claim unless the wording is strictly pertinent to a specific claim. It would be appreciated though that EFSA may consider and comment generally on such elements relating to wording to ensure the compliance with the criteria laid down in the Regulation.

In doing so the explanation provided for in recital 16 of the Regulation on the notion of the average consumer should be recalled. In addition, such assessment should take into account the particular perspective and/or knowledge in the target group of the claim, if such is indicated or implied.

TERMS OF REFERENCE

HEALTH CLAIMS OTHER THAN THOSE REFERRING TO THE REDUCTION OF DISEASE RISK AND TO CHILDREN'S DEVELOPMENT AND HEALTH

EFSA should in particular consider, and provide advice on the following aspects:

- Whether adequate information is provided on the characteristics of the food pertinent to the beneficial effect.
- Whether the beneficial effect of the food on the function is substantiated by generally accepted scientific evidence by taking into account the totality of the available scientific data, and by weighing the evidence. In this context EFSA is invited to comment on the nature and quality of the totality of the evidence provided according to consistent criteria.
- The specific importance of the food for the claimed effect. For functions affected by a large number of dietary factors whether a reference to a single food is scientifically pertinent.

In addition, EFSA should consider the claimed effect on the function, and provide advice on the extent to which:

- the claimed effect of the food in the identified function is beneficial.
- a cause and effect relationship has been established between consumption of the food and the claimed effect in humans and whether the magnitude of the effect is related to the quantity consumed.

- where appropriate, the effect on the function is significant in relation to the quantity of the food proposed to be consumed and if this quantity could reasonably be consumed as part of a balanced diet.
- the specific study group(s) in which the evidence was obtained is representative of the target population for which the claim is intended.
- the wordings used to express the claimed effect reflect the scientific evidence and complies with the criteria laid down in the Regulation.

When considering these elements EFSA should also provide advice, when appropriate:

- on the appropriate application of Article 10 (2) (c) and (d) in the Regulation, which provides for additional labelling requirements addressed to persons who should avoid using the food; and/or warnings for products that are likely to present a health risk if consumed to excess.

APPENDIX B

EFSA DISCLAIMER

The present opinion does not constitute, and cannot be construed as, an authorisation to the marketing of the food/food constituent, a positive assessment of its safety, nor a decision on whether the food/food constituent is, or is not, classified as foodstuffs. It should be noted that such an assessment is not foreseen in the framework of Regulation (EC) No 1924/2006.

It should also be highlighted that the scope, the proposed wordings of the claims and the conditions of use as proposed in the Consolidated List may be subject to changes, pending the outcome of the authorisation procedure foreseen in Article 13(3) of Regulation (EC) No 1924/2006.

APPENDIX C

Table 1. Main entry health claims related to sodium, including conditions of use from similar claims, as proposed in the Consolidated List.

ID	Food or Food constituent	Health Relationship	Proposed wording
336	Sodium/salt.	Effects on blood pressure.	En kost med låg salthalt kan bidra till ett hälsosamt lågt blodtryck.
		Target group: whole population.	A diet low in salt may promote a healthy low blood pressure.
		<u>Clarification provided</u> Reducing NaCl consumption helps to maintain healthy blood pressure.	<u>Clarification provided</u> En kost med låg salthalt kan bidra till ett hälsosamt lågt blodtryck. A diet low in salt may promote a healthy low blood pressure.
Conditions of use - ab 200 mg/l Natrium und 200 mg/l Chlorid (siehe EG-Mineralwasser-Richtlinie). - Vähendatud soolasisaldus kooskõlas 1924/2006 lisas toodud toitumisalase väitega. Toidukäitleja tootes soolasisaldus mitte üle 0,7 g/100g.			
Comments from Member States Reducing NaCl consumption helps to maintain healthy blood pressure. NB! Sweden wishes to withdraw its part of the claim 336, but the parts by Estonia and Germany remain.			
ID	Food or Food constituent	Health Relationship	Proposed wording
705	Low sodium/ salt and/ or increased potassium. Low sodium/ salt and/ or increased potassium.	Heart health.	Diet low in sodium and increased potassium helps maintain blood pressure; a nutritionally balanced diet with a low sodium/salt content maintains blood pressure, thereby promoting artery and heart health.
		<u>Clarification provided</u> Maintenance of healthy blood pressure.	<u>Clarification provided</u> Diet low in sodium and increased potassium helps maintain blood pressure; a nutritionally balanced diet with a low sodium/salt content maintains blood pressure, thereby promoting artery and heart health.
		Conditions of use - Must meet minimum requirements, as per Annex to Regulation 1924/2006.	
ID	Food or Food constituent	Health Relationship	Proposed wording
1148	Food reduced/ low in/ free of sodium/salt and/ or increased potassium.	Blood pressure, heart health. <u>Clarification provided</u> Cardiovascular health: Helps maintain healthy	Diet low in sodium and increased potassium helps maintain blood pressure. [X] can be part of a low sodium/ salt diet to help maintain blood pressure, thereby promoting artery and heart

		blood pressure.	health. <u>Clarification provided</u> Diet low in sodium and increased potassium helps maintain blood pressure. [X] can be part of a low sodium/ salt diet to help maintain blood pressure, thereby promoting artery and heart health.
Conditions of use - Meet the relevant annex requirements in HC Regulation			
ID	Food or Food constituent	Health Relationship	Proposed wording
1178	Breads with salt content of <0.7%. <u>Clarification provided</u> New: Bread with fat content max 7 g/100 g and mono and disaccharides max 10 g/100 g fresh weight.	Cardiovascular system.	Helps to control blood pressure.
Conditions of use - Breads with salt content of <0.7%.			
Comments from Member States Food composition defined.			
ID	Food or Food constituent	Health Relationship	Proposed wording
1185	Natural berries/sodium.	Cardiovascular system.	Natural berries contain very little sodium, so they are also safe and healthy for those who monitor their blood pressure.
Conditions of use - Natural berries with a sodium content of 0.2-3.5mg/100g = daily dose.			
ID	Food or Food constituent	Health Relationship	Proposed wording
1420	Low sodium/ salt and/ or increased potassium.	Heart health. <u>Clarification provided</u> Maintenance of healthy blood pressure.	Diet low in sodium and increased potassium helps maintain blood pressure. A nutritionally balanced diet with a low sodium/salt. Content maintains blood pressure, thereby promoting artery and heart health. <u>Clarification provided</u> Diet low in sodium and increased potassium helps maintain blood

			pressure; a nutritionally balanced diet with a low sodium/salt content maintains blood pressure, thereby promoting artery and heart health.
	Conditions of use - Must meet minimum requirements, as per Annex to Regulation 1924/2006.		
	Comments from Member States Must meet minimum requirements, as per Annex to Regulation 1924/2006.		